refer to the location of, the following information: The dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used.

§ 820.185 Critical devices, device history record.

In addition to the requirements of § 820.184, the following requirements apply to critical devices: There shall be a critical device history record for each control number, which shall include complete information relating to the production unit. This record shall identify the specific label, labeling, and control number used for each production unit and shall be readily accessible and maintained by a designated individual(s). The device history record shall include, or refer to the location of, the following:

(a) *Component documentation.* The documentation of each critical component used in the manufacture of a device shall include:

(1) *Control number.* The control number designating each critical component or lot of critical components used in the manufacture of a device.

(2) *Acceptance record.* The acceptance record of the critical component, including acceptance date and signature of the recipient.

(b) *Record of critical operation.* The record of, or reference to, each critical operation, identifying the date performed, the designated individual(s) performing the operation and, when appropriate, the major equipment used.

(c) *Inspection checks.* The inspection checks performed, the methods and equipment used, results, the date, and signature of the inspecting individual.

§ 820.195 Critical devices, automated data processing.

When automated data processing is used for manufacturing or quality assurance purposes, adequate checks shall be designed and implemented to prevent inaccurate data output, input, and programming errors.

§ 820.198 Complaint files.

(a) Written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device shall be reviewed, evaluated, and maintained by a formally designated unit. This unit shall determine whether or not an investigation is necessary. When no investigation is made, the unit shall maintain a record that includes the reason and the name of the individual responsible for the decision not to investigate.

(b) Any complaint involving the possible failure of a device to meet any of its performance specifications shall be reviewed, evaluated, and investigated. Any complaint pertaining to injury, death, or any hazard to safety shall be immediately reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint file.

(c) When an investigation is made, a written record of each investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include the name of the device, any control number used, name of complainant, nature of complaint, and reply to complainant.

(d) Where the formally designated unit is located at a site separate from the actual manufacturing establishment, a duplicate copy of the record of investigation of any complaint shall be transmitted to and maintained at the actual manufacturing establishment in a file designated for device complaints.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Tracking Requirements

Subpart C—Additional Requirements and Responsibilities